510(k) SUMMARY
CELL-DYN®3500 Multi-Parameter Automated Hematology Analyzer

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING A SUBSTANTIALLY EQUIVALENT DETERMINATION

The following information as presented in the Premarket Notification (510(k) for the Cell-Dyn® 3500 Hematology Analyzer constitutes data supporting a substantially equivalent determination.

Substantial equivalence has been demonstrated between the Cell-Dyn 3500 and the Coulter® ZBI (marketed prior to May 1976), Coulter Hemoglobinometer (marketed prior to May 1976), the Coulter Model S (marketed prior to May 1976), and the Coulter Model S Plus IV, Premarket Notification #K823355.

Intended Use

The Cell-Dyn 3500 is a multi-parameter, hematology analyzer designed for In-Vitro diagnostic use in clinical laboratories.

Device Description

The Cell-Dyn 3500 is a table-top analyzer consisting of the main analyzer, data station, and printer. An optional Sample Loader can be attached to the analyzer to transport samples in racks for automated processing.

The instrument has two sampling modes: Open Sample Aspiration Mode and Closed Sample Aspiration Mode. The instrument has the capability of diluting a sample for a CBC including a 5-part WBC differential for a total of 20 parameters. The 20 reportable parameters are as follows:

White blood cells (WBC), red blood cells (RBC), platelets (PLT), percent of neutrophils (%N), number of neutrophils (NEU), percent of lymphocytes (%L), number of lymphocytes (LYM), percent of monocytes (%M), number of monocytes (MONO), percent of eosinophils (%E), number of eosinophils(EOS), percent of basophils (%B), number of basophils(BASO), hemoglobin (HGB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red cell distribution width (RDW) and mean platelet volume (MPV).

Principles of Operation

The Shear valve isolates a precise volume of whole blood by means of a shearing action as the front and rear sections rotate. The aspirated blood is isolated in three separate segments - one for the WOC dilution, one for the WIC/HGB dilution and one for the RBC/PLT dilution. The WOC segment is diluted with the sheath reagent. The WIC/HGB segment is diluted with the diluent and WIC/HGB lyse reagent is added to lyse the RBCs. The RBC/PLT segment is diluted with the diluent.

The instrument then measures, using the electrical impedance method, the number and size of cells present per volume of whole blood for RBC and PLT. It measures, using laser optical methods, the number of WBCs (WOC or WBC Optical count) present per volume of whole blood, and using electrical impedance (WIC or WBC Impedance count). It derives, using light scattering measurements, values for: %N, %L, %M, %E and %B. It derives, using electrical impedance measurements, values for: MCV, RDW, MPV, PDW, and, calculates, using appropriate measured or derived data, the values for: NEU, LYM, MONO, EOS, BASO, HCT, MCH, MCHC and PCT.

Similarities and Differences

The methods of determination are those used by the Coulter® ZBI, Coulter, Hemoglobinometer, Coulter Model S, Coulter Model S Plus Series, Coulter STKS and the manual microscopic differential count. These methods collectively perform one or more of the determinations which are combined in the Cell-Dyn® 3500.

The Cell-Dyn 3500 differs from the above instruments in that it combines optical (WOC) and impedance (WIC) methods in order to provide a more accurate WBC count in the presence of certain interfering substances (such as lyse-resistant RBCs). Additionally, the Cell-Dyn 3500 monitors the optical WBC count to detect and flag the presence of fragile WBCs and mathematically correct the count for their presence.

In addition, as a response to the demand for environmentally safe cyanide-free products, the HGB/WIC lysing reagent has been modified to remove the cyanide compound. A new methemoglobin method has been developed using hydroxyalamine as the direct oxidant replacing cyanide. This new cyanide-free method produces HGB results that correlate well with cyanide-containing methods.

Finally, the shear valve has been modified with the addition of a loop aspiration system to enhance reliability and require less maintenance.

Equivalency Data

The data compiled to support the claim that the CELL-DYN 3500 is substantially equivalent to the Coulter Model S Plus IV includes accuracy, precision, linearity and carryover. The Cell-Dyn 3500 WBC differential has been compared to the NCCLS reference microscopic manual differential method for accuracy.

The accuracy, precision and linearity data shows performance to manufacturer's specifications. The data supports our claim that the Cell-Dyn 3500 is substantially equivalent to the Coulter S+IV. The modifications of the instrument are intended to enhance the safety and effectiveness of the Cell-Dyn 3500 and demonstrate substantial equivalence to the Coulter S Plus IV and Cell-Dyn 3500, #K913305/A.

Conclusion

In conclusion, the Cell-Dyn 3500 update shows an evolution of the technology used that is similar to the technology used in the Coulter S Plus IV, Coulter ZBI, Coulter Hemoglobinometer, and the Coulter Model S series.

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